

REMARKS

In response to the above Office Action, claims 1 and 12 have been amended to more specifically define the amine of the claimed salt of the carbostyryl derivative as an amine selected from the group consisting of an amino acid; a C₁₋₆ alkyl-substituted amine which may have a substituent selected from the group consisting of a hydroxy group and an amino group; and an amino sugar. Support for this can be found on page 6, lines 9-12 and page 6, line 23 to page 7, line 4 of the specification.

In the Office Action, the Examiner rejected claims 1-21 under 35 U.S.C. § 102(b) for being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) for being obvious over cited patents to Yamasaki, Uchida, Urashima and Matsuda. The Examiner argues that these references all teach the instantly claimed carbostyryl derivative and its salts, and though they do not teach the specific amine salts claimed, it would be obvious to one skilled in the art to change one salt for another pharmaceutically acceptable salt in the compound.

As acknowledged by the Examiner, none of the references teach the specific amine salts now claimed in claims 1 and 12. Accordingly, it is submitted that neither amended claims 1 nor 12 or claims 2-11 and 13-21 dependent therefrom can be anticipated by any of the references. Their withdrawal as a ground of rejection of the claims under § 102(b) is therefore requested.

The salts of the present invention are composed of a compound of formula (1) and the specific amines claimed because Applicants found that the solubility of these salts is unexpectedly higher than that of base-free compounds. Namely, the solubility of the compound of formula (1) drastically increased 83-fold to 14333-fold by making the

compound into the specific amine salt thereof (see the tables in Examples 8 and 9 of the specification).

This is totally unexpected and is not suggested by any of the teachings of any of the cited prior art references. As noted in M.P.E.P § 716.02(c), evidence of unexpected results can overcome a prima facie case of obviousness.

The unexpected results are obviously beneficial because they provide good water-solubility to the carbostyryl derivative. The good solubility provides a variety of merits to the carbostyryl derivative, which are described in the specification at page 20, line 15 to page 21, line 7. More specifically, "The amine salts of carbostyryl derivative of the present invention have a superior water solubility, and are useful for the preparation in the form of a solution such as injections, ophthalmic solutions, oral solutions, enemas, gargles, ear drops, nasal drops, external liquid preparations and the like. Especially, they have some advantages such as being easy to keep the uniformity of content; not necessary to control the particle distribution; not necessary to add the suspending agent, dispersing agent and the like, each to carry out the terminal sterilization by steam or the sterilization by filtration; etc. and thus the desired pharmaceutical products and be prepared industrially, simply and easily. Especially, the ophthalmic solutions of the invention have some advantages, for example, not to need the complicated re-dispersion like a suspension preparation, and good feelings in use such as good looks."

Accordingly, it is submitted that neither amended claims 1 nor 12 or claims 2-11 and 13-21 dependent therefrom can be considered to be obvious over any of these

references. Their withdrawal as a ground of rejection of the claims under § 103(a) is therefore requested.

It is believed claims 1-21 are now in condition for allowance.


In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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